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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,859	09/02/1999	JAMES SAMSOONDAR	5352-051	4860

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EXAMINER

SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
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1743

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DATE MAILED: 03/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/367,859

Applicant(s)
Samsouondar

Examiner
Arlen Soderquist

Art Unit
1743



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 5, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

1. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1 an interferant is a relative thing since it interferes with the analysis of another component of a sample. Since there are no steps for measuring an analyte in claim 1 the process is either lacking steps related to the analysis of the analyte or the interferant is actually the analyte for claim 1 and the claims which are dependent therefrom. For examination purposes the interferant will be treated as the analyte since calling it an interferant does not change the fact that it is the only thing that a concentration is being determined. The analyte appears to play no part in the analysis which is occurring in claim 1 or the claims dependent therefrom including the equations used in claims 3 or 6. If in fact the analyte is relevant to one or more of the listed wavelengths or constants then claims 3 and 6 are incomplete since the analyte is not identified. Relative to claims 2 and 4 it is not clear if they further limit the scope of claim 1. In claim 1 the specimen appears to be defined as containing a selected interferant, at least one analyte, a blood substitute and one or more other interferants or, if examiner has counted correctly, at least four compounds. In claim 2 the selected interferant is defined as a blood substitute dropping the minimum number of compounds in the specimen to three. In claim 4 the one or more other interferants is defined as a blood substitute which again appears to reduce the minimum number of compounds in the specimen to three. Thus claims 2 and 4 have a scope which appears to exceed the scope of claim 1. As a part of this it is not clear if the blood substitute in claims 2 and 4 is the same blood substitute as in claim 1.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagusa in view of Christenson, Leissing or Mullins, Gimpel (newly cited and applied) and Simon. In the patent Sagusa teaches a colorimetric method for samples including interfering chromogens. Color former is added to blood serum sample color it, and measurements for specific components are determined based on the light absorbance caused by coloring. For one sample, a differential light absorbance between two wavelengths at each of long wavelength region, middle wavelength region and short wavelength region within a visible wavelength band is determined. The degree of chyle is determined from the measurements for the long wavelength region, the degree of hemolysis is determined from the measurements for the middle wavelength region, and the degree of icterus is determined from the measurements for the short wavelength region. The measurements for the specific components are then corrected by the degree of chyle, degree of hemolysis and degree of icterus to obtain highly correct measurements. Sagusa does not teach interference by blood substitutes, using derivative spectroscopy in the correction equation or detection of pseudohemolysis.

In the abstract Christenson discusses hemoglobin based blood substitutes and their interference with routine chemical tests.

In the abstract Leissing discusses modification of clinical chemistry methods to overcome interferences from diaspirin crosslinked hemoglobin (DCLHb).

In the paper Mullins discusses effects of Fluosol-DA (artificial blood) on clinical chemistry tests and instruments. Artificial blood must be added to the list of therapeutic agents that produce interference with diagnostic laboratory tests. Fluosol-DA (Alpha Therapeutic Corp., Los Angeles, CA), a stable 20% emulsion of perfluorocarbons in aqueous medium, is being evaluated in clinical trials as a blood substitute in the United States. They investigated its effects in blood and serum samples on test results and instruments in the clinical chemistry laboratory. The 20% emulsion was added to blood or serum specimens in amounts corresponding to the replacement of in-vivo plasma volumes of 10-50%, concentrations that would be expected in blood samples obtained from patients who have received Fluosol. Observed interferences mimicked those caused by high triglyceride concentrations in serum specimens: interference with chemical reactions and generation of spurious absorbance readings because of turbidity. These types of errors are often additive, and the cumulative effect may cause either erroneously high or low values for the analytes concerned. Because Fluosol may be used widely, although infrequently, for patients refusing blood transfusions on religious grounds and for patients with rare antibodies to red blood cells who require transfusion, laboratories analyzing specimens containing Fluosol should be aware of the potential errors.

In the paper Gimpel teaches a reference interval for the bilirubin excess in cerebrospinal fluid by derivative spectrophotometry. The value of the bilirubin excess can be a useful aid for recognizing blood from hemorrhage in cerebrospinal fluid. One of the parameters needed for the calculation of the bilirubin excess is the total bilirubin concentration in cerebrospinal fluid. A method for measuring total bilirubin in cerebrospinal fluid is presented, based on diazotization of bilirubin according to Jendrassik-Grof, combined with multiwavelength first-derivative spectrophotometry. This bilirubin assay allows determination of total bilirubin concentrations as low as $0.045 \mu\text{mol/L}$. This method also enables a correlation for oxyHb interference. The value of the bilirubin excess was calculated for patients not showing any neurological disorder. A reference interval of $0.07 \pm 0.06 \mu\text{mol/L}$ was calculated for the bilirubin excess. Particularly

relevant to the instant claims is the calculations and equations shown in the right column of page 218.

In the paper Simon discusses a "pseudo-hemolytic" transfusion reaction caused by intravenous iron-dextran therapy. Intravenous iron-dextran therapy can cause a red-brown discoloration of the plasma, simulating a hemolytic transfusion reaction. A rapid and simple test to differentiate between true hemolysis and plasma discoloration due to circulating iron-dextran complexes is described.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include substances such as blood substitutes recognized by Christenson, Leissing or Mullins as interfering substances into the Sagusa correction method because of the recognized possibility for interference with clinical chemistry tests and the projected use of these substances in humans. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Sagusa method to differentiate between true hemolysis and plasma discoloration due to circulating colored substances as taught by Simon because of the ability to select wavelengths that will allow the effects of one chromogen to be removed from another chromogen as taught by Sagusa and the need to differentiate between true hemolysis and plasma discoloration due to circulating substances as taught by Simon. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a derivative spectroscopic method as shown by Gimpel for correction in the Sagusa method because of the ability to differentiate between interfering substances such as the hemoglobin and bilirubin of Gimpel. Determination of specific wavelengths would be a results effective variable which has been held to be within the skill of the routineer in the art by the Courts (see *In re Boesch*, 205 USPQ 215 (CCPA 1980)).

5. Applicant's arguments filed November 5, 2001 have been fully considered but they are not persuasive. Relative to the lack of clarity, it appears that applicant is trying to claim a general method of determining the concentration of a substance in the presence of other substances which interfere with the measurement or overlap the spectrum. The rejection is attempting to show that the language used will not distinguish a substance which interferes with another substance and an

analyte that is interfered with by other substances unless there are steps directed to the measurement of the analyte in addition to the interfering substance. Thus claims 1-7 are being treated without a determination if the substance being measured is the interfering substance or the analyte. In other words calling something an interferant fails to distinguish the substance from an analyte when it is the only substance that is required to be measured by the claimed steps. Thus applicant's arguments that a reference is not teaching the measurement of a "selected interferant" is without merit because there is not any requirement to measure the presence or concentration of another compound as the "analyte". Additionally there is still some clarity lacking relative to what is required to be present in the sample and the scope of the dependent claims relative to independent claim one.

Examiner agrees that no single reference anticipates the claims. However, the Sagusa reference clearly teaches methods for dealing with interfering compounds in analyses in blood samples. Thus a teaching that blood substitutes are known or expected to interfere with chemical tests as found in Christenson, Leissing or Mullins would have motivated one of skill in the art to use the methods of Sagusa to overcome interference from the blood substitutes in the circumstances that the blood substitutes would have been expected to interfere. In the same manner the teachings relative to the pseudo-hemolytic behavior of the iron-dextran therapy substances would have motivated one of skill in the art to make measurements to distinguish or differentiate between real hemolysis and the pseudo-hemolysis caused by a substance or medication that was being administered to a person or patient because it would allow the proper care to be given. The newly cited and applied Gimpel reference clearly shows use of first derivative spectroscopy to remove the influence of interfering substances in a manner being claimed.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additional art relates to correction of spectra using first derivative spectroscopy or due to the presence of interfering substances such as blood substitutes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The

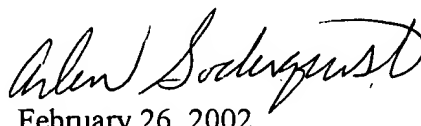
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examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are 703-872-9310 (before finals), 703-872-9311 (after-final), 703-305-7718, 703-305-5408 and 703-305-5433. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



February 26, 2002

ARLEN SODERQUIST
PRIMARY EXAMINER